

IN THE UNITED STATES PATENT OFFICE

Applicant : Jacques THILLY et al.
Appl. No. : 10/566,615
Int. Appl. No. : PCT/EP04/08703
Int. Filing Date : 2 August 2004
Title : *Novel Device*

Grp./A.U. : To be assigned
Examiner : To be assigned
Conf. No. : 7423

Docket: : VB60431USw

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS
UNDER 35 U.S.C. 371**

The following is in response to the Notification of Missing Requirements dated May 23, 2006. Applicants hereby request a 2-month extension of time to extend the response period up to and including September 23, 2006. The Commissioner is hereby authorized to charge such fees and any other fees required or credit any overpayment to Deposit Account No. 07-1392.

A Listing of the Claims in the Preliminary Amendment Filed With the Application appear on page 2 of this document.

Remarks appear on page 7 of this document.

LISTING OF CLAIMS IN THE PRELIMINARY AMENDMENT FILED WITH THE APPLICATION

Amendments to the claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Original) An elastomer material having an absorption coefficient for laser light of $0.5 - 2.5 \text{ mm}^{-1}$.
2. (Original) An elastomer material according to claim 1 comprising a base thermoplastic elastomer compounded with a colourant to have the absorption coefficient for laser light of $0.5 - 2.5 \text{ mm}^{-1}$.
3. (Currently Amended) An elastomer material according to ~~claim 1 or~~ claim 2 wherein the base thermoplastic elastomer has a melting point of 200°C or less.
4. (Currently Amended) An elastomer material according to claim 2 ~~or 3~~ wherein the base thermoplastic elastomer is a styrene-ethylene/butylene-styrene thermoplastic elastomer, or a styrene/butadiene/styrene tri-block copolymer or styrene-(butadiene/butylene)-styrene tri-block copolymer.
5. (Currently Amended) An elastomer material according to claim 2, ~~3 or 4~~ wherein the base thermoplastic elastomer is selected from the materials Evoprene™, Cawiton™, and C-Flex.
6. (Currently Amended) An elastomer material according to ~~any one of claims 2 to 5~~ claim 2 wherein the colourant comprises a pigment or mixture of pigments mixed with a carrier material.

7. (Currently Amended) An elastomer material according to claim 6 wherein the pigment or mixture thereof has the colour Pantone 5497C, 556C, 5565C, 563C, 570C, 5555C or a similar grey or grey-green colour.
8. (Currently Amended) An elastomer material according to ~~6 or~~ claim 7 wherein the colourant comprises a mixture of the pigments (:) white 6, black 7, green 7 and blue 29.
9. (Currently Amended) An elastomer material according to claim ~~6, 7 or 8~~ wherein the carrier material comprises ethylene vinyl acetate, low density polyethylene or polypropylene
10. (Currently Amended) An elastomer material according to ~~any of the claims 7 to 10~~ to claim 6 wherein the colourant comprises 10 – 50 wt.% pigment, the balance up to 100% comprising the carrier material.
11. (Currently Amended) An elastomer material according to ~~any of the claims 7 to 11~~ to claim 6 comprising 1 – 15wt.% of colourant the balance up to 100% comprising the base thermoplastic elastomer.
12. (Currently Amended) An elastomer material according to claim 1 which comprises Evoprene™ Super G, compounded with 1 – 5 wt% of a colourant masterbatch comprising an ethylene vinyl acetate carrier with 35 - 45wt% of pigment of a colour Pantone 5497C, 556C, 5565C, 563C, 570C, 5555C or a similar grey or grey-green colour.
13. (Currently Amended) An elastomer material according to claim 1 which comprises Evoprene™ TS2525, compounded with 1 – 5 wt% of a colourant master batch comprising an ethylene vinyl acetate carrier with 35 - 45wt% of

pigment of a colour colour Pantone 5497C, 556C, 5565C, 563C, 570C, 5555C or a similar grey or grey-green colour.

14. (Currently Amended) An elastomer material according to claim 1 which comprises Cawiton™ PR5947, compounded with 3 - 15 wt% of a colourant master batch comprising an LDPE carrier with 15 – 20 wt% of pigment of a colour Pantone 5497C, 556C, 5565C, 563C, 570C, 5555C or a similar grey or grey-green colour.

15. (Currently Amended) An elastomer material according to ~~one of the preceding claims~~ claim 1 which in a thickness ca 2mm allows less than 6% of laser power up to 8W incident power to pass through.

16. (Currently Amended) An elastomer material according to ~~one of the preceding claims~~ claim 1 having an absorption coefficient ~~in the range of~~ of 1.0 – 2.5 mm⁻¹.

17. (Currently Amended) An elastomer material according to ~~claim 16~~ claim 1 having an absorption coefficient of 1.5 – 2.2 mm⁻¹.

18. (Currently Amended) An elastomer material according to ~~claim 18~~ claim 1 having an absorption coefficient of 1.4 – 1.6 mm⁻¹.

19. (Currently Amended) A closure for a pharmaceutical vial made wholly or partly of an elastomer material as claimed in ~~any one of the preceding claims~~ in claim 1.

20. (Original) A closure for a pharmaceutical vial having a closure wall comprised of an elastomer material such that when laser light is directed on the

outer surface of the closure wall 99% of the laser power is absorbed within 0.5 – 2.5 mm depth from the outer surface with the effect of melting the material.

21. (Currently Amended) A closure for a pharmaceutical vial, made wholly or partly of a thermoplastic elastomer compounded with a colourant to the extent that less than 6% of laser light of wavelength 980nm at an incident laser power up to 8W penetrates through the closure to reach the interior of the vial or syringe.

23. (Currently Amended) A process for introducing a substance into a vial comprising: providing a vial having a mouth opening closed by a closure as claimed in ~~any one of claims 19 to 21~~ claim 19, passing a hollow needle through the closure, introducing ~~a~~ the substance into the vial via the needle, withdrawing the needle from the vial and closure, and sealing the residual puncture hole in the closure by heat sealing.

24. (Currently Amended) A ~~The~~ process according to claim 23 wherein the ~~heating~~ heat sealing of the elastomer material of the closure adjacent the puncture site so that the material fuses is done by directing laser light onto the elastomer material adjacent the puncture site.

25. (Currently Amended) A ~~The~~ process according to claim 24 wherein the laser light has a power less than 20W.

26. (Currently Amended) A ~~The~~ process according to claim 25 wherein the laser light has a power 4 – 10W.

27. (Currently Amended) A ~~The~~ process according to ~~any one of claims 24 to 26~~ claim 24 wherein the laser ~~beam~~ light has a wavelength in the range of 960-1000nm.

28. (Currently Amended) A The process according to ~~any one of claims 24 to 27~~ claim 24 wherein the laser light is directed at the elastomer material adjacent to the puncture site for a period of 0.5 – 2 seconds.

REMARKS / ARGUMENTS

Claims 1-28, as filed in the Preliminary Amendment on January 31, 2006, are pending in this application.

The Notification of Missing Requirements dated May 23, 2006, requires an oath or declaration of the inventors, a surcharge of \$130 for late submission of an oath or declaration, and additional claims fees of \$460 as follows:

\$100 for 10 claims over 20
\$360 for multiple dependent claim surcharge

Applicants hereby submit a Declaration of the inventors along with a surcharge of \$130. However, Applicants further submit that no multiple dependent claims were present in the Preliminary Amendment filed with the application, and there are only 8 claims over 20, which the proper fees were paid at the time of filing the application.

In a telephone conversation with Vonda Wallace of the USPTO, claim 28 was identified as being a multiple dependent claim. In the listing of claims in the Preliminary Amendment, claim 28 is dependent on claim 24 only.

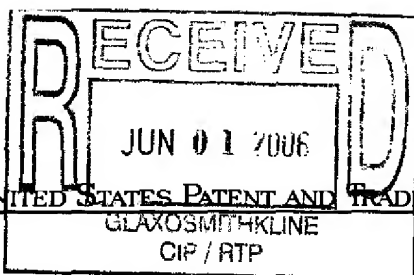
In view of the above, Applicants request that the additional claims fees of \$460 be removed from the requirements set forth in the Notification of Missing Requirements.

Respectfully submitted,

Dated: August 28, 2006

/Michael M. Conger/

Michael M. Conger
Attorney for Applicant
Reg. No. 43,562
Tel. (919) 483-2474
Fax. (919) 483-7988



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

COPIED TO THE UK
VPM / MNC / RFW / marj

U.S. APPLICATION NUMBER NO. 10/566,615	FIRST NAMED APPLICANT Jacques Thilly	ATTY. DOCKET NO. VB60431
---	---	-----------------------------

INTERNATIONAL APPLICATION NO. PCT/EP04/08703

I.A. FILING DATE 08/02/2004	PRIORITY DATE 08/04/2003
--------------------------------	-----------------------------

20462
SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

23 July 2006 (n)

CONFIRMATION NO. 7423
371 FORMALITIES LETTER



Date Mailed: 05/23/2006

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 01/31/2006
- Copy of the International Search Report filed on 01/31/2006
- Preliminary Amendments filed on 01/31/2006
- Information Disclosure Statements filed on 01/31/2006
- Request for Immediate Examination filed on 01/31/2006
- U.S. Basic National Fees filed on 01/31/2006
- Priority Documents filed on 01/31/2006
- Specification filed on 01/31/2006
- Claims filed on 01/31/2006
- Abstracts filed on 01/31/2006
- Drawings filed on 01/31/2006

2006 MAY 30 P 1:12

RECEIVED
SMITHKLINE BEECHAM

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of \$460 as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath

or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is **\$590** for a Large Entity:

- **\$130** Surcharge.
- Total additional claim fee(s) for this application is **\$ 460**
 - **\$100** for 10 total claims over 20.
 - **\$360** for multiple dependent claim surcharge.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

VONDA M WALLACE

Telephone: (703) 308-9140 EXT 225

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/566,615	PCT/EP04/08703	VB60431